

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
8 June 2006 (08.06.2006)

PCT

(10) International Publication Number  
**WO 2006/060821 A1**

(51) International Patent Classification:

A61M 16/04 (2006.01) A61M 25/02 (2006.01)  
A61B 1/24 (2006.01) A62B 9/06 (2006.01)

(21) International Application Number:

PCT/US2005/044200

(22) International Filing Date:

5 December 2005 (05.12.2005)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

60/632,806 3 December 2004 (03.12.2004) US

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

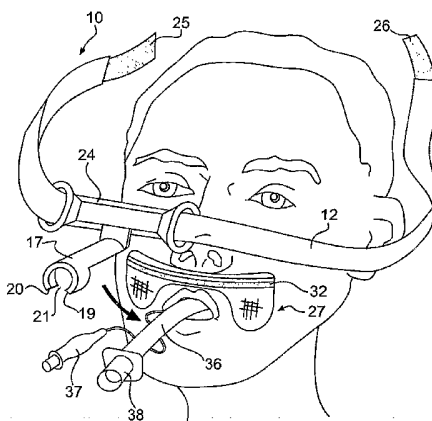
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ENDOTRACHEAL TUBE HOLDER



(57) Abstract: A tube holder assembly (10) is provided for securing a medical tube such as an endotracheal tube (36) to a patient. In one illustrative embodiment, the holder assembly comprises a support strap (12) for placement around the patient's head or neck region, a bracket (11) for holding the endotracheal tube in position relative to the patient's mouth, and a face anchoring portion (27) for securing the support strap to the patient's face region. The support strap includes a front surface (22) and an opposed, back surface (23). The bracket may be attached to the front surface of the support strap. The bracket may include an upper bar (17) and an arm (19) extending from the upper bar. The face anchoring device may comprise a first surface (28a) configured to adhere to the patient's face region, and a second, opposed surface (28b) having a strap-engaging portion configured to mechanically engage the back surface of the support strap. The support strap may be configured to be repeatedly releasable and adjustable to the face anchoring device.

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**ENDOTRACHEAL TUBE HOLDER****CROSS-REFERENCE TO RELATED APPLICATIONS**

[0001] This application claims priority to U.S. provisional application no. 60/632,806 filed on December 3, 2004, the contents of which are hereby incorporated in its entirety by reference.

**BACKGROUND**

[0002] Endotracheal (ET) tubes are commonly used to ventilate patients for resuscitation, anesthesia and other critical care procedures. These patients are usually critically ill and unable to breathe on their own. Once inserted, it is desirable to secure the endotracheal tube in a fixed position to prevent movement of the tube or extubation of the tube from the patient's airway.

[0003] Traditionally, endotracheal tubes have been secured to the patient by placing adhesive tape on the tube and affixing it to the patient's cheek or face. In some cases twill ties have been used, either alone or in combination with adhesive tape. Commercially available adhesive tape-type products for use with an endotracheal tube holder tend to sag and lift off the patient's face after limited use. Further, because the tape must be removed frequently for suctioning and repositioning, considerable skin irritation and possible infection can occur. Endotracheal tube securing devices which incorporate a biteblock are also available, but have not received widespread acceptance since biteblocks tend to irritate the patient's mouth and tongue after a short period of use.

[0004] More importantly, the endotracheal tube is often connected to a heavy, bulky breathing circuit along with a closed tracheal suction catheter, which tends to place a significant load strain and tension, or pulling force, on the endotracheal tube securing device. Also, humidifiers, water condensate traps, and oxygen lines, which may be part of the breathing circuit, add to the weight and tension exerted on the endotracheal tube. In such cases, purely adhesive tape-type products cannot withstand the constant load strain, leading to the tube coming out of position, sagging, or kinking. This misplacement or deformation of

the tube can cause the airway to become partially shut off and results in the loss or reduction of administered ventilation to the patient.

[0005] Likewise, a rigid bite block-type endotracheal tube securing device suffers from similar problems in that the tube tends to bend or kink at the securement junction where the tube connects to the ventilator circuit and/or catheter. Often, the suction catheter or ventilator circuit will need to be moved or adjusted, causing the kinking of the endotracheal tube due to the weight of the attached equipment and the failure of the securement junction to flex or bend in response to the clinician's manipulation of the equipment.

[0006] Accordingly, there is a need for a lightweight, comfortable, easy to use securing device for an endotracheal tube which does not require a bite block, yet will provide maximum tube security and prevents kinking.

### **SUMMARY OF THE INVENTION**

[0007] One illustrative embodiment of the present invention provides a holder assembly for securing a medical tube, such as for example, an endotracheal tube, to a patient's mouth. The holder assembly comprises a support strap for placement around the patient's head or neck region, a bracket for holding the endotracheal tube in position relative to the patient's mouth, and a face anchoring portion for securing the support strap to the patient's face region. The support strap includes a front surface and an opposed, back surface. The bracket may be attached to the front surface of the support strap. The bracket may include an upper bar and an arm extending from the upper bar. The face anchoring device may comprise a first surface configured to adhere to the patient's face region, and a second, opposed surface having a strap-engaging portion configured to mechanically engage the back surface of the support strap. The support strap may be configured to be repeatedly releasable and adjustable to the face anchoring device.

[0008] In another exemplary embodiment, a holder assembly for securing an endotracheal tube to a patient's mouth is provided. The holder assembly may comprise a support strap for placement around the patient's head

or neck region, a bracket for holding the endotracheal tube in position relative to the patient, and a face anchoring device configured to adhere to the patient's face region and attachable to the support strap for secure engagement of the strap to the patient's face region. The bracket may include an upper bar and an arm extending from the upper bar. The arm may terminate in a gripping region configured to form a snap-fitting engagement around the endotracheal tube.

[0009] In still yet another exemplary embodiment, a holder assembly for securing an endotracheal tube to a patient's mouth is provided. The holder assembly may comprise a support strap for placement around the patient's head or neck region, a bracket affixed to the support strap for holding the endotracheal tube in position relative to the patient, and a face anchoring device configured to adhere to the patient's face region and attachable to the support strap for secure engagement of the strap to the patient's face region. The bracket may comprise an upper bar and an arm extending generally perpendicular from the upper bar. The arm may terminate in a gripping region including tabs for forming a snap-fitting engagement around the endotracheal tube.

[0010] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only, and are not restrictive of the invention, as claimed.

### **BRIEF DESCRIPTION OF THE DRAWINGS**

[0011] The following drawings, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the invention and together with the description, serve to explain the principles of the invention.

[0012] FIG. 1 is a perspective view of a bracket/neckband component of an exemplary endotracheal tube holder assembly, according to one embodiment consistent with the principles of the present invention.

[0013] FIG. 2 is a perspective view of the face adherent portion of the tube holder assembly of FIG. 1.

[0014] FIG. 2A is a side view of the face adherent portion of FIG. 2.

[0015] FIG. 3 is a perspective view of a partially assembled tube holder assembly of FIGS. 1 and 2.

[0016] FIG. 4 shows an assembly step of further securing a tube to a portion of the tube holder assembly of FIG. 3 using tape.

[0017] FIG. 5 is a rear view of the tube holder assembly of FIG. 4 depicting the support strap around a patient's neck.

[0018] FIG. 6 is a perspective view of a fully assembled endotracheal tube holder assembly of FIG. 1 relative to a patient and being connected with other ventilation circuit equipment.

[0019] FIG. 7 is a perspective view of a bracket/neckband component of an exemplary endotracheal tube holder assembly, according to another embodiment consistent with the principles of the present invention.

[0020] FIG. 8 is a rear view of a face adherent portion of the tube holder assembly of FIG. 7.

[0021] FIG. 9 is a perspective view of a partially assembled tube holder assembly of FIGS. 7 and 8.

[0022] FIG. 10 shows an assembly step of further securing a tube to a portion of the tube holder assembly of FIG. 9 using tape.

[0023] FIG. 11 is a perspective view of a bracket/neckband component of an exemplary endotracheal tube holder assembly, according to still another embodiment consistent with the principles of the present invention.

[0024] FIG. 12 is an underside perspective view of the bracket/neckband component of FIG. 11.

[0025] FIG. 13 is a side-view of an assembled endotracheal tube holder assembly of FIG. 11.

[0026] FIG. 14 is a perspective view of an exemplary bracket of a tube holder assembly incorporating a bite block, according to yet another embodiment consistent with the principles of the present invention.

[0027] FIG. 15 is a perspective view of the molded one piece bracket with bite block of FIG. 14 attached to a support strap.

[0028] FIG. 16 is a perspective view of a bracket/neckband component of an exemplary endotracheal tube holder assembly, according to even still another embodiment consistent with the principles of the present invention.

### **DETAILED DESCRIPTION**

[0029] A holder assembly is disclosed herein for securing a medical tube, such as for example, an endotracheal tube, to a patient. The holder assembly may comprise two or more components that cooperate to securely position an endotracheal tube against a patient's mouth. As shown in an exemplary embodiment depicted in FIG. 1, one component of the tube holder assembly 10 may include an elongated support strap or neckband 12 for placement around the patient's head or neck region. The support strap or neckband 12 may be made from a soft, comfortable yet strong material such as Velcro™ loop pile fabric which is flexible and comfortable. The neckband 12 may have a front surface 22 and an opposed, back surface 23, both made from Velcro™ loop pile fabric material. In one exemplary embodiment, the neckband 12 may be about 1 inch wide and about 30 inches long. Further, the neckband 12 may terminate at both ends into releasably attachable closure ends 25 and 26. These closure ends 25 and 26 may be sewn onto the neckband 12, and may include mechanical engagement surfaces for engaging the front surface 22 of the neckband 12. For example, the mechanical engagement surfaces may comprise Velcro™ hook fabric or material to interlock and engage the Velcro™ loop pile fabric of the front surface 22 of the neckband 12.

[0030] The tube holder assembly 10 may also comprise another component, such as a bracket 11, for holding the endotracheal tube in position

relative to the patient's mouth. The bracket **11** may be, for example, a semi-flexible injection molded clear bracket **11**. In one aspect, the bracket **11** may be injection molded in one piece from, for example, 95 shore A durometer semi-flexible blue tinted clear non-DEHP polyvinyl chloride (PVC) plastic, although other appropriate plastic materials may also be used. As shown in **FIG. 1**, the bracket **11** may include an upper bar **13** extending approximately four inches in total length and about  $\frac{1}{2}$  inch wide. Slots **14** and **15** may be provided at both ends of upper bar **13**. These slots **14** and **15** may be molded with the upper bar **13**, and in one embodiment may be dimensioned about  $\frac{3}{4}$  inches high and about .200 inches wide.

[0031] Extending downward from upper bar **13** is a bridge **16** that can be, for example, about 0.500 inch wide. Projecting forwardly and outwardly from bridge **16** is a tube securing extension or arm **17** that can be, for example, about  $1\frac{1}{2}$  inches long. As illustrated, the arm **17** may extend generally perpendicular to the upper bar **13**. The arm **17** may be integral with the upper bar **13**, or alternatively, the arm **17** may be formed as a separate component. The extension or arm **17** may have a generally semi-circular contour with a built-in undercut portion **18** which terminates in a gripping region **21** comprising distal snap-in tabs **19** and **20** for snap-fitting engagement around the endotracheal tube. The tabs **19** and **20** may be flexible, and are configured to encircle a tube diameter of about .450 inches. Accordingly, the gripping portion **21** may accommodate all sizes of endotracheal tubes from size 5 up to size 10. The tabs **19** and **20** serve to snap over and retain the endotracheal tube onto the holder extension or arm **17**. If desired, the extension or arm **17** may include a surface feature for enhanced engagement with the endotracheal tube and with an adhesive tape, if desired. For example, the surface feature may comprise a surface roughening, barbs, teeth, or adhesive on the undercut portion **18** or other surface contacting the endotracheal tube. In one aspect, the surface roughening may comprise about a .003 inch deep pebble finished texture molded onto the surface, which forms a friction fit non-slip engagement with the endotracheal tube along with an added gripping surface for optional placement of the adhesive tape.

[0032] As illustrated in **FIG. 1**, the neckband **12** may be threaded through dual slots **14** and **15** of the bracket **11** such that a portion **24** of the support strap **12** rests behind the upper bar **13** and the bracket **11** is attached to the front surface **22** of the support strap or neckband **12**. In the embodiment shown, the neckband **12** can slide and be adjusted through the bracket **11** by way of dual slots **14** and **15** until the bracket **11** is centrally located on support strap **12**. Alternately, the bracket **11** may also be affixed to the neckband **12**, such as for example, by sewing the bracket **11** to the front surface **22** of the support strap **12**.

[0033] **FIGS. 2** and **2A** illustrate yet another component of the tube holder assembly **10** comprising a face anchoring device **27** that cooperates with the support strap or neckband **12** to maintain the endotracheal tube in position relative to the patient's mouth. In one aspect, the face anchoring device **27** may be formed from a woven skin-colored fabric material, such as for example, Bioflex<sup>TM</sup> material 715P manufactured by Scapa Corp. The device **27** may be, for example, about 6 inches long and may comprise a central band portion **29** with cheek pads **30** and **31** on either side of the central band portion **29**. The device **27** may comprise a first surface **28a** configured to adhere to the patient's face region, and a second, opposed surface **28b** having a strap-engaging portion configured to mechanically engage the back surface **23** of the support strap **12** for securing the strap **12** to the patient's face region. As shown in **FIG. 2**, the second surface **28b** may include a Velcro<sup>TM</sup> hook strip **32** about 3/8 inch wide. This hook strip **32** serves as a complementary mating element to the mating element or Velcro<sup>TM</sup> loop pile fabric on the back surface **23** of the neckband **12**, forming an interlocking relationship between the two. The first surface **28a** of the device **27** may include a release liner **33** which can extend to upper extended release liner **34**, which extends past the upper edge **45** of surface **28b** to better enable gripping of the release liner. Once the extended release liner **34** is peeled back, it exposes skin-friendly adhesive **35** on the first surface **28a** of the device **27**. It should be noted that a crack and peel release liner can easily be substituted for the extended release liner **34**, if desired. In another aspect, the face anchoring device **27** may be die cut to its final shape, as shown.



[0034] **FIG. 3** depicts a partially assembled view of the tube holder assembly **10** of **FIGS. 1** and **2**. A face anchoring device **27** has been adhered to the patient's face region, as shown. In this embodiment, the Velcro™ hook strip **32** part of the device **27** extends the full width of the device **27**. The portion **24** of neckband **12** behind the bracket **11**, made from Velcro™ loop pile material, may be placed directly onto the mating Velcro™ hook strip **32** of the face anchoring device **27**. The endotracheal tube **36** may be snapped onto the bracket extension or arm **17** such that the snap-in tabs **19** and **20** engage around the endotracheal tube **36** (including the pilot balloon tube **37** part of the tube **36**). In this manner, the neckband **12** may form an interlocking, strong mechanical connection with the mating hook strip **32** on the face anchoring device **27**. Such a configuration enables the support strap **12** to be repeatedly releasable and adjustable with respect to the face anchoring device **27**. As shown, the endotracheal tube **36** may terminate with a standard adapter **38**.

[0035] For additional reinforcement, tape may be applied around the endotracheal tube **36** and the extension or arm **17**, as shown in **FIG. 4**. For example, a foam tape **39** having an extended release liner **40** at one end and a non-adherent mylar tab **42** at another end may be applied. Once the liner **40** is peeled back it exposes an adhesive **41** which may be used to wrap the tube **36** around the bracket extension or arm **17** at undercut portion **18**. Thus, the foam tape **39** securely adheres to both the bracket extension **17** and tube **36**.

[0036] Once the endotracheal tube **36** is in place, the closure ends **25** and **26** of the support strap **12** may be secured onto the front surface **22** of the strap **12**, as shown in **FIG. 5**. As illustrated, the end of the strap **12** may be secured in an interlocking, criss-cross arrangement to form a tight, secure fit behind the neck or head region of the patient. The closure ends **25** and **26** can easily be lifted off neckband **12** for easy adjustment of the tightness of the neckband **12**.

[0037] **FIG. 6** shows a fully assembled tube holder assembly **10** comprising a neckband **12** adhered to a face anchoring device **27** with foam tape **39** wrapped around the bracket arm **17**. Once assembled, the neckband **12** can

remain securely fixed to the face anchoring device **27** to prevent any dislodgement or movement of the endotracheal tube **36**. The criss-cross arrangement of the ends of the neckband **12**, as shown in **FIG. 5**, further prevents any load strain or tension acting to pull out the tube **36** from the mouth or airway of the patient. It is contemplated that the bridge **16** extending from the upper bar **13** of the bracket **11** will act as a pivot point such that the extension or arm **17** can flex slightly from side to side without kinking the endotracheal tube **36**. Unlike with rigid extensions or arms on bite blocks of prior art devices, the bridge **16** of the present invention prevents the endotracheal tube **36** from bending or kinking. Further, it is contemplated that the heavy weight of a closed tracheal suction catheter **43** and connected ventilation circuitry, as partially depicted, will not pull out the endotracheal tube **36** with the use of this tube holder assembly **10**. If repositioning of the endotracheal tube **36** is desired, the closure ends **25** and **26** on the neckband **12** and the portion **24** of the strap **12** behind the bracket **11** can be released and, as such, repeatedly repositioned as desired.

[0038] In addition, the lift tab **42** on the foam tape **39** can provide a convenient, easy manner for removal of the tape **39** from the extension or arm **17**. The endotracheal tube **36** can be repositioned inward or outward from the trachea as needed, and a new piece of foam tape **39** or other suitable hospital-supplied tape can be used to resecure the tube **36** to the extension or arm **17**. As such, the endotracheal tube **36** can be repositioned easily while providing easy access to the oral cavity of the patient for care or suctioning.

[0039] **FIG. 7** illustrates a component of another exemplary embodiment of a tube holder assembly **50** in accordance with the present invention. As shown, the component comprises a neckband or support strap **49** and a bracket **51** affixed to the strap **49**. The neckband **49** may be formed of a soft, plush nylon tricot loop material on a front surface **58** and opposed, back surface **60**. Sandwiched between both front and back surfaces **58** and **60** there can be provided a cushioned polyurethane foam core **59**. Like the neckband **12** of **FIG. 1**, the neckband **49** may terminate into closure ends **61** and **62** comprising Velcro™ hook material. Unlike in **FIG. 1**, the bracket **51** of the present embodiment may be permanently affixed onto the support strap or neckband **49**

by side stitching, such as for example, through the upper bar **52** at locations **56** and **57**. The bracket **51** may be centrally located on the neckband **49** so as to form a unitary component of the tube holder assembly **50**.

[0040] In one aspect, the bracket **51** may be a one-piece injection molded bracket **51** formed from blue tinted clear non-DEHP polyvinyl chloride plastic with a slightly softer more flexible durometer of 85 shore A. The bracket **51** may be similar to bracket **11**, and can include an upper bar **52** dimensioned about 0.500 inches wide by about 2 inches long and about .070 inches in thickness. Downwardly extending from the upper bar **52** is a bridge **53** which extends into extension or arm **54**. As illustrated, the arm **54** may extend generally perpendicular to the upper bar **52** and terminate in a gripping region comprising flexible tabs **55** to allow a snap-fitting engagement of the endotracheal tube **36** to the arm **54**. The arm **54** may be integral with the upper bar **52**, or alternatively, may be formed as a separate component. Like the extension or arm **17** of FIG. 1, the arm **54** may have a generally semi-circular contour with a built-in undercut portion that may include a surface feature for enhanced engagement with the endotracheal tube. For example, the surface feature may comprise a surface roughening, barbs, teeth, or adhesive.

[0041] FIG. 8 illustrates a rear view of a face anchoring device **63** similar to the face anchoring device **27** of FIG. 1 for use with the tube holder assembly **50** of the present invention. The face anchoring device **63** may have dual crack and peel score lines **64** and **65** which permit convenient removal of a top release liner portion **66**, leaving lower portions **67** and **68** for easy positioning using gloved hands by the clinician. This makes for convenient positioning and adherence of the face anchoring device **63** to the patient's face region.

[0042] FIG. 9 shows a partially assembled tube holder assembly **50** of FIG. 7 in accordance with an exemplary embodiment of the present invention. A face anchoring device **63** has been adhered to the patient's face region, as shown. As with face anchoring device **27**, a Velcro™ hook strip **72** may extend across the width of the device **63**. The back surface **60** of the neckband **49**, comprising a mating element of Velcro™ loop pile material **70**, may be placed

onto the complementary mating element or hook strip **72** of the face anchoring device **63**. The endotracheal tube **36** may be snap-fitted onto the arm **54** of the bracket **51** in a manner similar to what was described for **FIG. 3**. As shown in **FIG. 10**, for additional reinforcement tape **78** may be applied around the endotracheal tube **36** and the extension or arm **54**. Any readily available hospital tape such as Duropore or Transpore may be used to wrap around bracket extension **54** to securely retain the endotracheal tube **36** in place.

[0043] **FIG. 11** depicts another embodiment of a bracket/neckband component of a tube holder assembly comprising a one-piece flexible PVC injection molded bracket **81** stitched onto a cushioned neckband **82**. The neckband **82** comprises front and back surfaces **83** and **84** formed of Velcro<sup>TM</sup> loop pile material, with a central polyurethane soft cushioned core **85** in between. The bracket **81** may include an upper bar **86** which can be stitched at locations **87** and **88** to the neckband **82**. Further, the bracket **81** can be configured to include a forwardly and outwardly extending curved bridge portion **89** which eliminates any direct pressure point of contact with the upper lip of the patient. A molded-in fillet **90** may also be provided and acts as a stabilizing fixture between the flat upper bar **86** and the curved bridge portion **89**, reinforcing both elements.

[0044] As illustrated, projecting forward from the bridge portion **89** can be a tapered extension **91**, which tapers from a dimension of about .500 inches at the bridge portion **89** to about .400 inches at its distal tip **92**. The length of the extension can be about 1.125 inches, which is long enough to accept a standard 1" wide hospital tape. The extension or arm **91** may have a uniformed, slightly curved underside **93** which can mate with the contours of adult endotracheal tubes from about 6 mm up to 10 mm in size. The top surface **94** of the extension **91** may have a molded-in textured pebble surface which provides a better gripping surface for placement of hospital tape compared to a typical, smooth molded surface.

[0045] **FIG. 12** shows an underside view of the bracket/neckband component **95** described and depicted in **FIG. 11**. The assembly **95** may include a tapered extension **96** having a pebble textured underside surface **97** for an

enhanced gripping engagement surface with a tube, similar to the tape gripping surface provided by pebble surface **94** depicted in **FIG. 11**. The underside surface **97** in **FIG. 12** may be also slightly contoured **98** to follow the radiused contour of the endotracheal tube. This radiused contour provides a maximum surface engagement with the round outer surface of the tube, such that the tape can form a positive compressive engagement between the bracket extension **96** and the various sized endotracheal tubes.

[0046] **FIG. 13** shows a side view of an assembled tube holder assembly **99** comprising a bracket/neckband component **95** of **FIGS. 11** and **12** and face anchoring device **100** adhered onto a patient's face region. As with previously described support straps or neckbands, the neckband **82** can include a Velcro<sup>TM</sup> compatible loop pile material on a back surface **83** which forms a locking mechanical engagement with a Velcro<sup>TM</sup> hook strip **103** on the face anchoring device **100**. Once the bracket extension or arm **94** has been taped onto the endotracheal tube **36**, the entire bracket/neckband component **95** functions to keep the tube **36** in a stable, secure position to prevent movement of the tube **36** within the patient's airway. As can be seen, forwardly and curvedly extending bridge portion **89** leaves an air gap or contact-free zone **107** with the patient's upper lip **108**. This provides patient comfort in preventing contact with the patient that could otherwise cause pressure sores, skin breakdown, and oral and facial infections, especially in long term intubated patients where the tube holder use may extend to as long as several weeks.

[0047] **FIG. 14** depicts an alternative embodiment of a bracket comprising a one-piece flexible injection molded bracket **109** which incorporates a molded-in rearward bite block **110** including a C-channel for insertion of the endotracheal tube. The C-channel may be configured to form a snap-fitted engagement with the tube. The surface of the bite block **110** may also include surface features, such as for example, surface roughening like a molded-in pebble finish **111** for enhanced engagement to the endotracheal tube. As shown in **FIG. 15**, the bracket **109** may be stitched onto a neckband **112** similar to those previously described, to form an assembly similar to that depicted in **FIG. 11**. The

C-channel feature can also be applied to other embodiments of the bracket disclosed herein.

[0048] **FIG. 16** illustrates yet another exemplary embodiment of a bracket/neckband component **120** consistent with the principles of the present invention. As illustrated, the component **120** comprises a neckband **122** similar in all respects to neckband **49** of **FIG. 7**. A bracket **130** may be affixed to the neckband **122** with stitches, similar to **FIG. 7**. Further, the bracket **130** may comprise an upper bar **132** from which a bridge portion **134** extends downwardly. The bridge portion **134** extends into a bracket extension or arm **136** that terminates into a gripping region **138** comprising flexible tabs **140** configured for snap-fitting engagement with an endotracheal tube. The bracket extension or arm **134** extends generally perpendicular from the upper bar **132**. In order to reduce the pressure point on the patient's lips when assembled, the bracket **130** further includes a contoured junction where the extension or arm **136** meets with the upper bar **132**, i.e., the underside of the bridge portion **134** includes chamfered corners **142**. This configuration creates an air gap or contact-free zone with the patient's upper lip, improving the patient's comfort and reducing chances for pressure sores, skin breakdown, and oral and facial infections. Reinforcement elements such as molded-in webs or walls **144** may be provided extending between the upper bar **132** and the extension or arm **136**, to prevent twisting or torqueing of the bracket **130**.

[0049] Lastly, a pediatric version of the tube holder assemblies described herein may be provided wherein the sizing of both the neckband and the various styles of bracket is miniaturized and/or dimensionally reduced to fit children between 2 years and up to 12 years old. The bracket/neckband component can therefore be dimensioned to securely hold pediatric endotracheal tubes from sizes 2 mm up to 6 mm. All this can be done without departing from the teachings of the disclosed invention.

[0050] It should be understood that the dimensions and materials described herein are provided merely as a guide to an acceptably sized and

constituted tube holder assembly, but can be varied from the measurements and materials specified without departing from the spirit of the invention.

[0051] It will be apparent to those skilled in the art that additional various modifications and variations can be made consistent with the present invention without departing from the scope or spirit of the invention. For example, various features within the several embodiments disclosed herein can be combined with features from other tube holder assembly embodiments. Other embodiments consistent with the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

[0052] What is claimed is:

## CLAIMS

1. A holder assembly for securing an endotracheal tube in a patient's mouth, the holder assembly comprising:
  - a support strap for placement around the patient's head or neck region, the support strap comprising a front surface and an opposed, back surface;
  - a bracket for attachment to the front surface of the support strap for holding the endotracheal tube in position relative to the patient's mouth, the bracket including an upper bar and an arm extending therefrom; and
  - a face anchoring device comprising a first surface configured to adhere to the patient's face region, and a second, opposed surface having a strap-engaging portion configured to mechanically engage the back surface of the support strap to secure the strap to the patient's face region;
2. The holder assembly of claim 1, wherein the bracket is affixed to the front surface of the support strap.
3. The holder assembly of claim 1, wherein the back surface of the support strap includes a mating element and the strap-engaging portion includes a complementary mating element to form an interlocking relationship.
4. The holder assembly of claim 3, wherein the mating element comprises a loop pile material, and the complementary mating element comprises a hook material.
5. The holder assembly of claim 1, wherein the arm extends generally perpendicular to the upper bar.
6. The holder assembly of claim 1, wherein the arm terminates in a gripping region configured to form a snap-fitting engagement around the endotracheal tube.



7. The holder assembly of claim 6, wherein the gripping portion comprises tabs configured for gripping the endotracheal tube.
8. The holder assembly of claim 7, wherein the tabs are flexible.
9. The holder assembly of claim 1, wherein the arm further comprises an undercut portion having a generally semi-circular contour.
10. The holder assembly of claim 1, wherein the arm further includes a surface feature for enhanced engagement with the endotracheal tube.
11. The holder assembly of claim 10, wherein the surface feature is selected from the group consisting of surface roughening, barbs, teeth, or adhesive.
12. The holder assembly of claim 1, wherein the upper bar comprises slots for placement of the support strap therethrough.
13. The holder assembly of claim 1, wherein the arm is integral with the upper bar.
14. The holder assembly of claim 1, wherein the junction between the upper bar and arm is contoured.
15. The holder assembly of claim 14, wherein the contoured junction is chamfered.
16. The holder assembly of claim 1, further including reinforcement elements extending between the upper bar and the arm.
17. The holder assembly of claim 1, wherein the support strap comprises releasably attachable closure ends.
18. The holder assembly of claim 17, wherein the closure ends include mechanical engagement surfaces for engaging the front surface of the support strap.

19. The holder assembly of claim 18, wherein the front surface of the support strap comprises a loop pile material and the mechanical engagement surfaces comprise hook material.
20. The holder assembly of claim 1, wherein the first surface of the face anchoring device comprises an adhesive.
21. The holder assembly of claim 1, further including an adhesive tape for securing the endotracheal tube to the arm.
22. The holder assembly of claim 21, wherein the adhesive tape comprises a foam tape.
23. The holder assembly of claim 1, wherein the upper bar comprises a portion of a bite block.
24. The holder assembly of claim 23, wherein the bite block includes a channel for insertion of the endotracheal tube.
25. The holder assembly of claim 24, wherein the channel is configured to form a snap-fitted engagement with the endotracheal tube.
26. A holder assembly for securing an endotracheal tube to a patient's mouth, the holder assembly comprising:
- a support strap for placement around the patient's head or neck region;
  - a bracket for holding the endotracheal tube in position relative to the patient, the bracket including an upper bar and an arm extending therefrom, the arm terminating in a gripping region configured to form a snap-fitting engagement around the endotracheal tube; and
  - a face anchoring device configured to adhere to the patient's face region and attachable to the support strap for secure engagement of the strap to the patient's face region.

27. The holder assembly of claim 26, wherein the face anchoring device comprises a strap-engaging portion configured to mechanically engage the support strap for securing the strap to the patient's face region.

28. The holder assembly of claim 27, wherein the support strap includes a mating element and the strap-engaging portion includes a complementary mating element to form an interlocking relationship.

29. The holder assembly of claim 28, wherein the mating element comprises a loop pile material, and the complementary mating element comprises a hook material.

30. The holder assembly of claim 26, wherein the support strap can be repeatedly releasable and adjustable to the face anchoring device.

31. The holder assembly of claim 26, wherein the arm extends generally perpendicular to the upper bar.

32. The holder assembly of claim 26, wherein the gripping portion comprises tabs configured for gripping the endotracheal tube.

33. A holder assembly for securing an endotracheal tube to a patient's mouth, the holder assembly comprising:

a support strap for placement around the patient's head or neck region;

a bracket affixed to the support strap for holding the endotracheal tube in position relative to the patient, the bracket including an upper bar and an arm extending generally perpendicular therefrom, the arm terminating in a gripping region including tabs for forming a snap-fitting engagement around the endotracheal tube; and

a face anchoring device configured to adhere to the patient's face region and attachable to the support strap for secure engagement of the strap to the patient's face region.

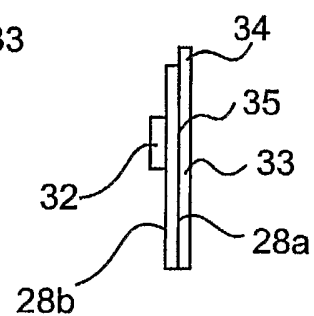
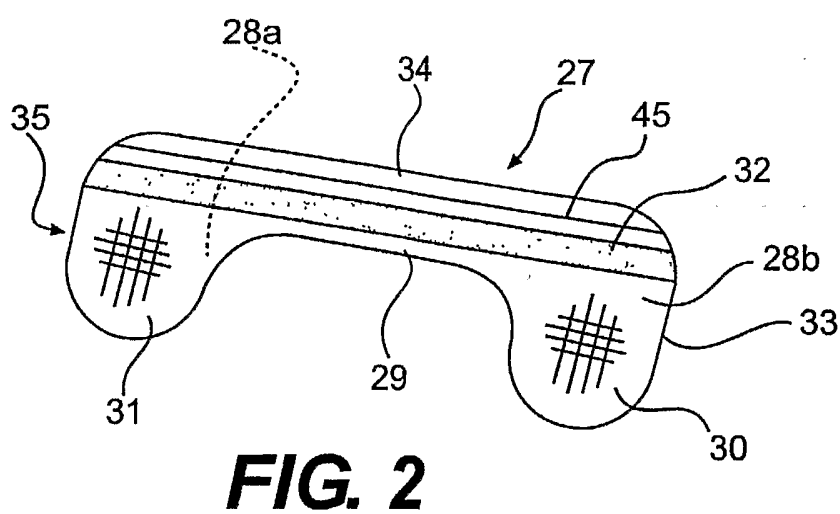
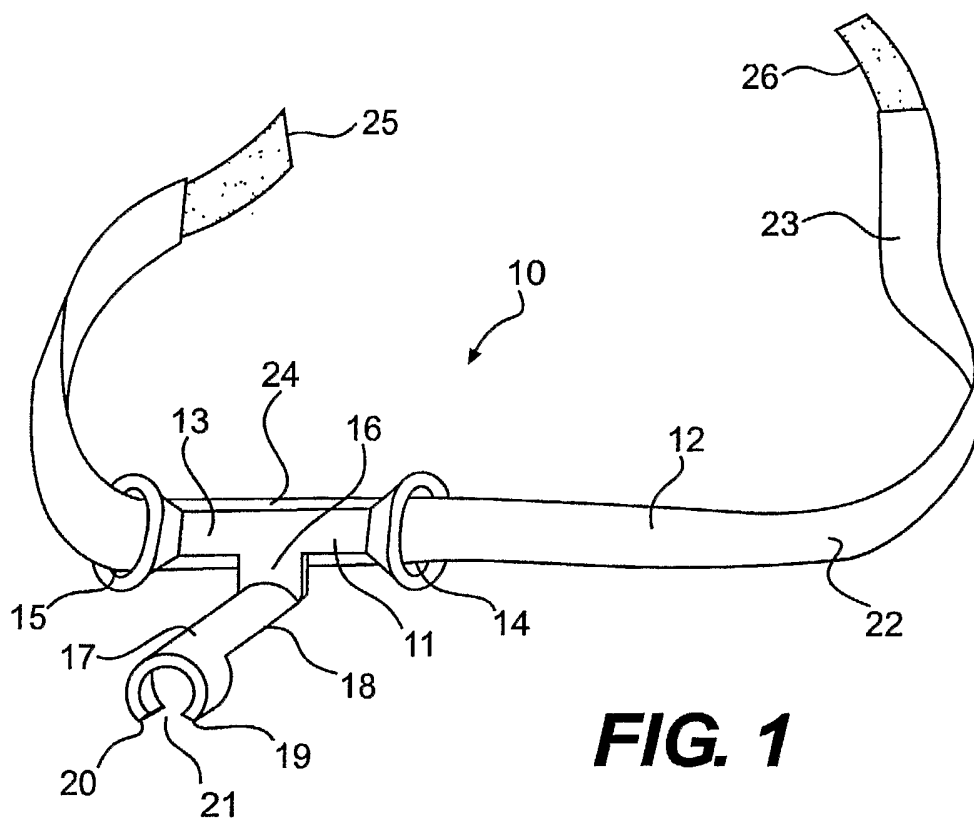
34. A holder assembly for securing a tube in a patient's mouth, the holder assembly comprising:

a support strap for placement around the patient's head or neck region;

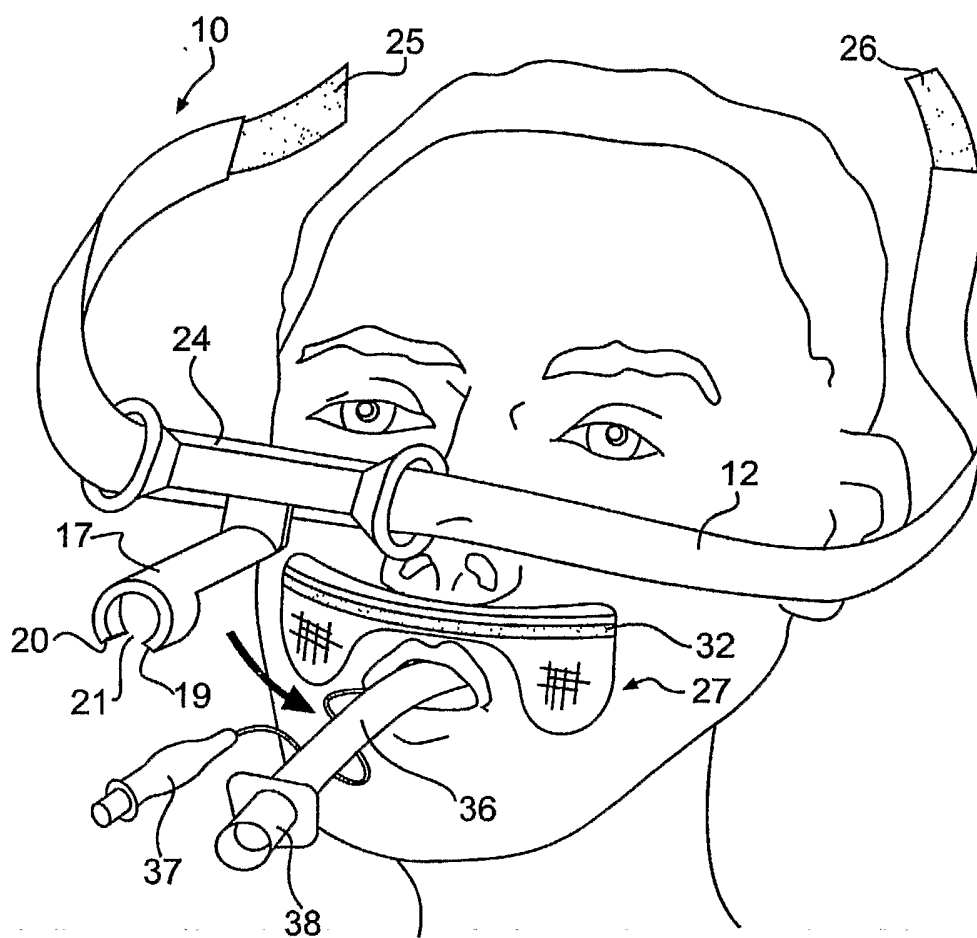
a bracket for attachment to the support strap for holding the tube in position relative to the patient's mouth; and

a face anchoring device to secure the support strap to the patient's face.

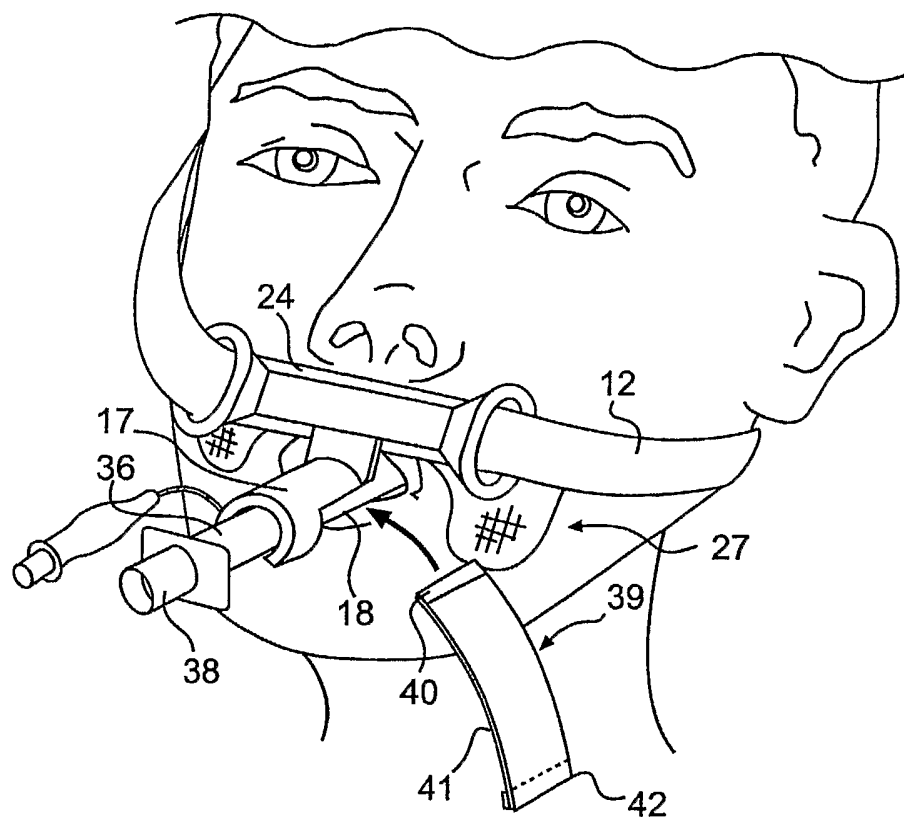
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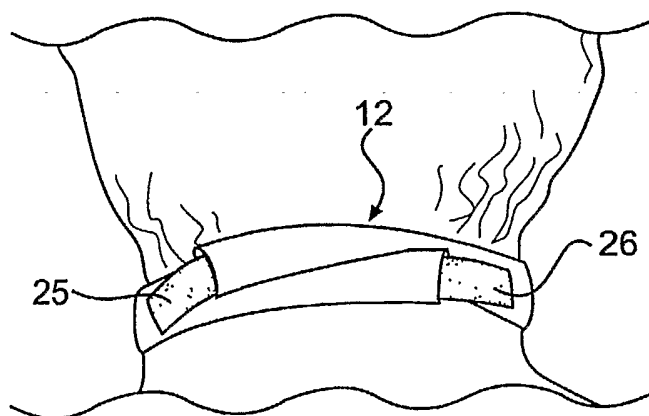
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**FIG. 3**

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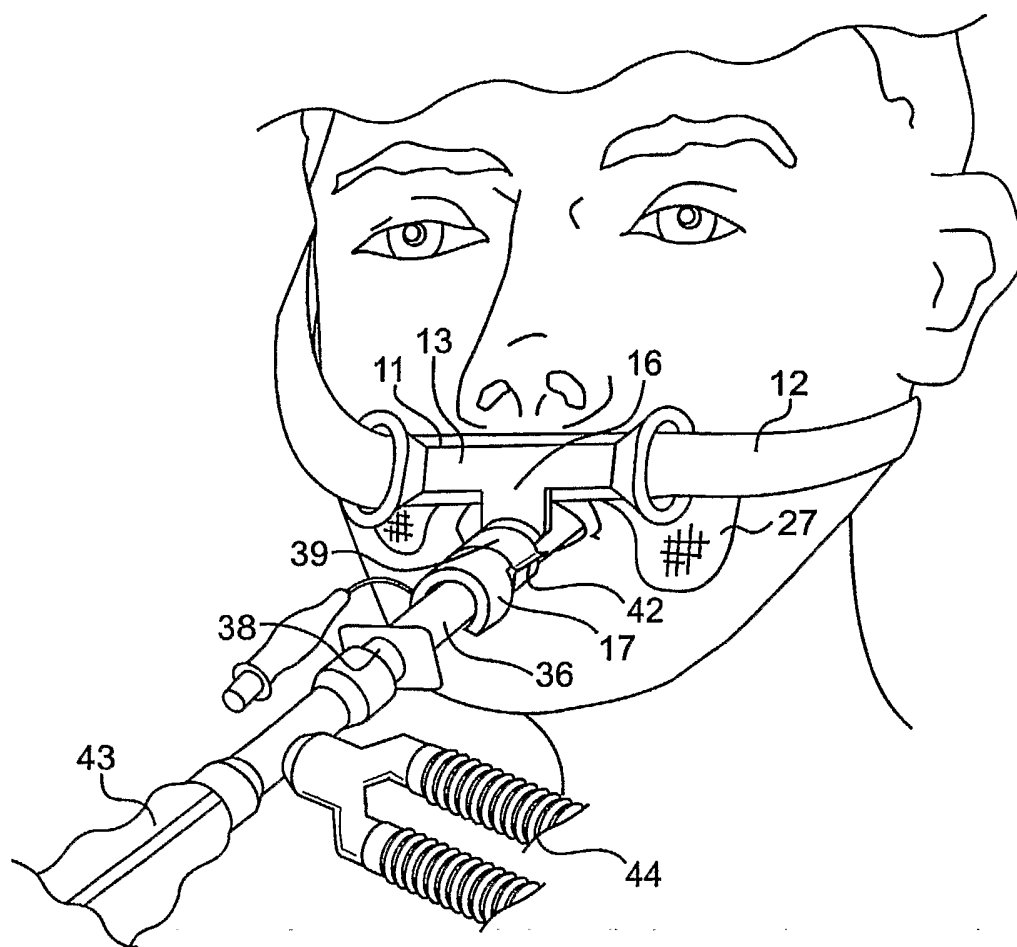


**FIG. 4**



**FIG. 5**

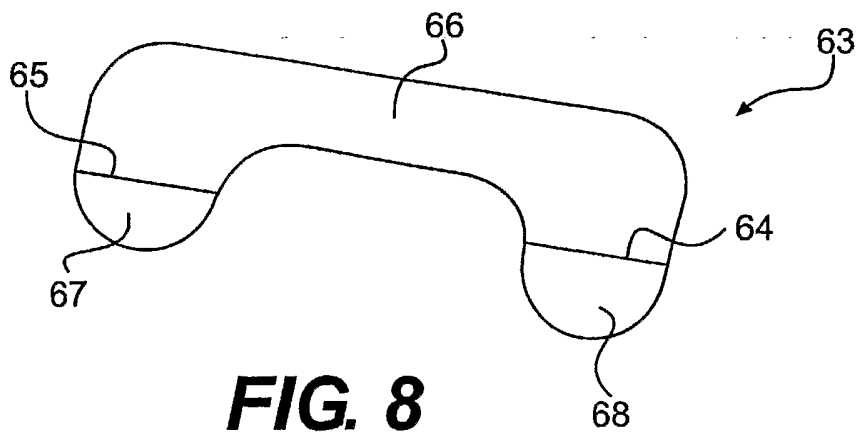
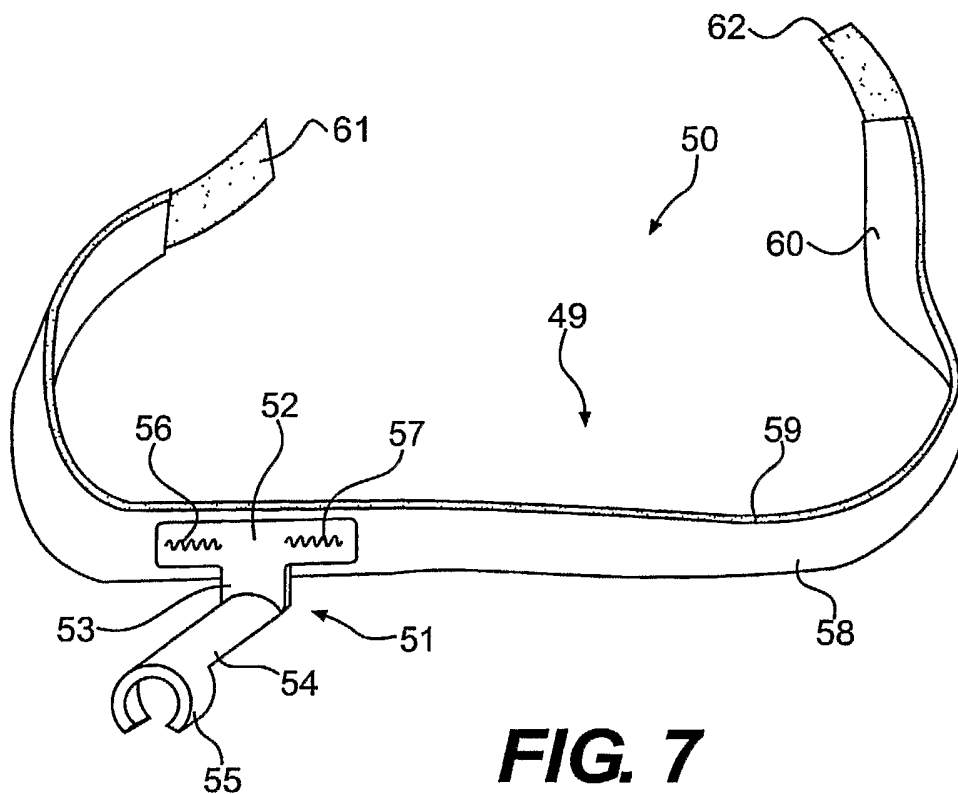
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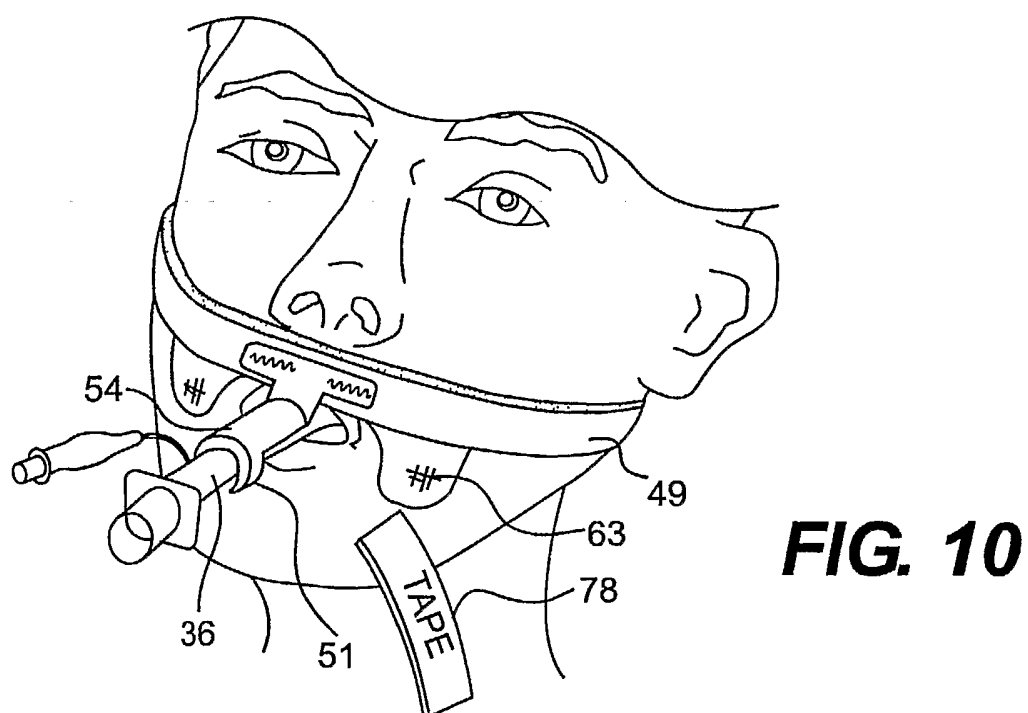
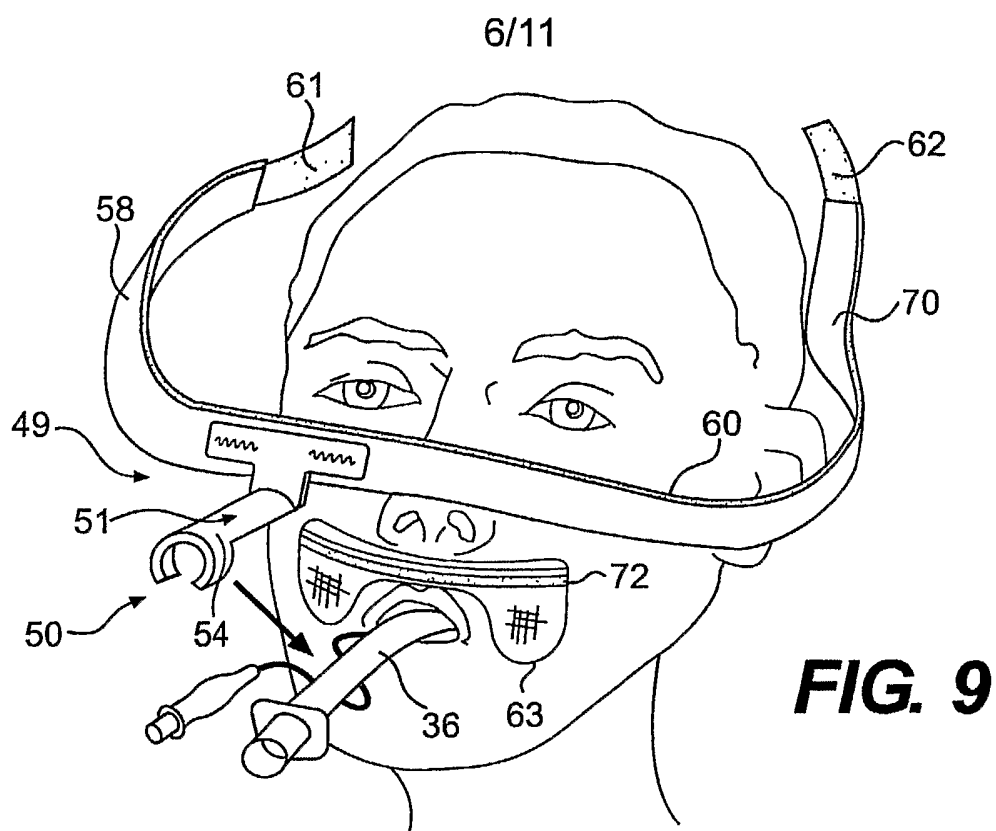


**FIG. 6**

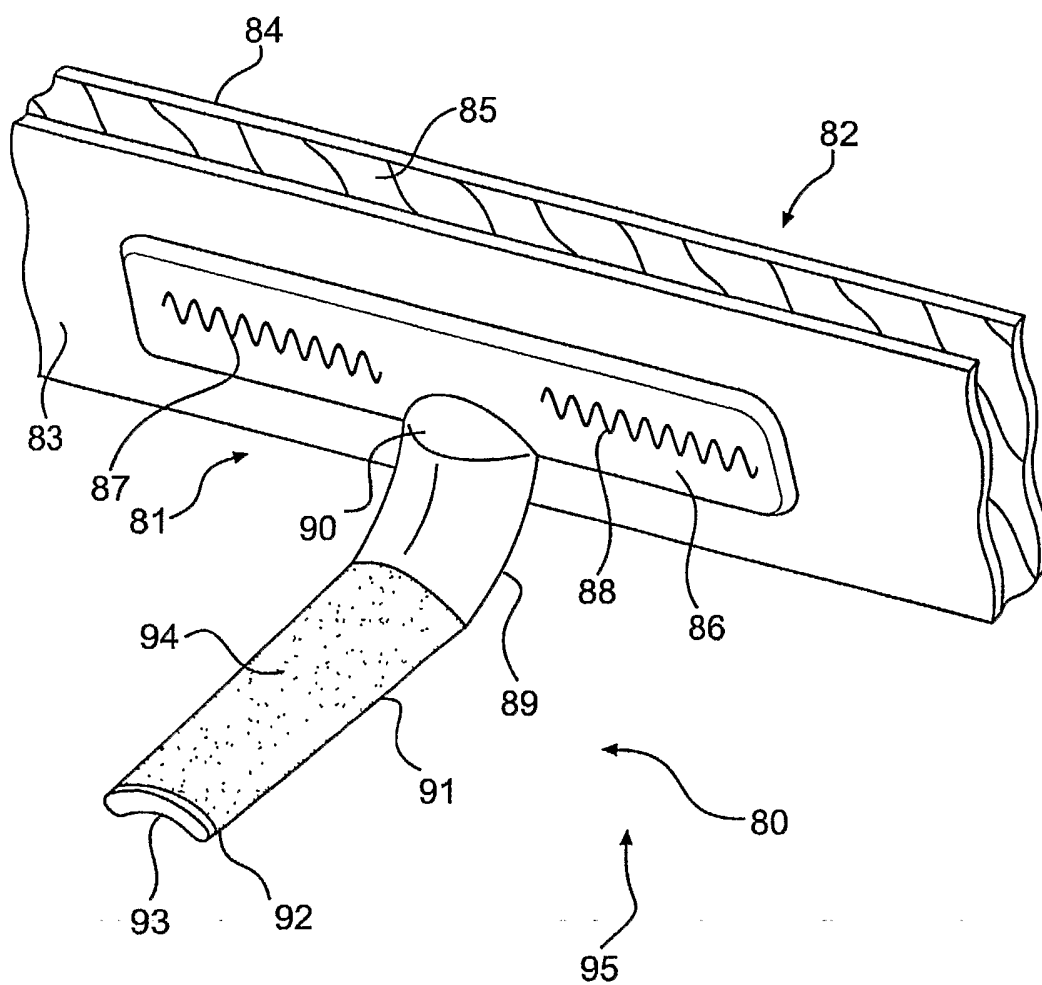


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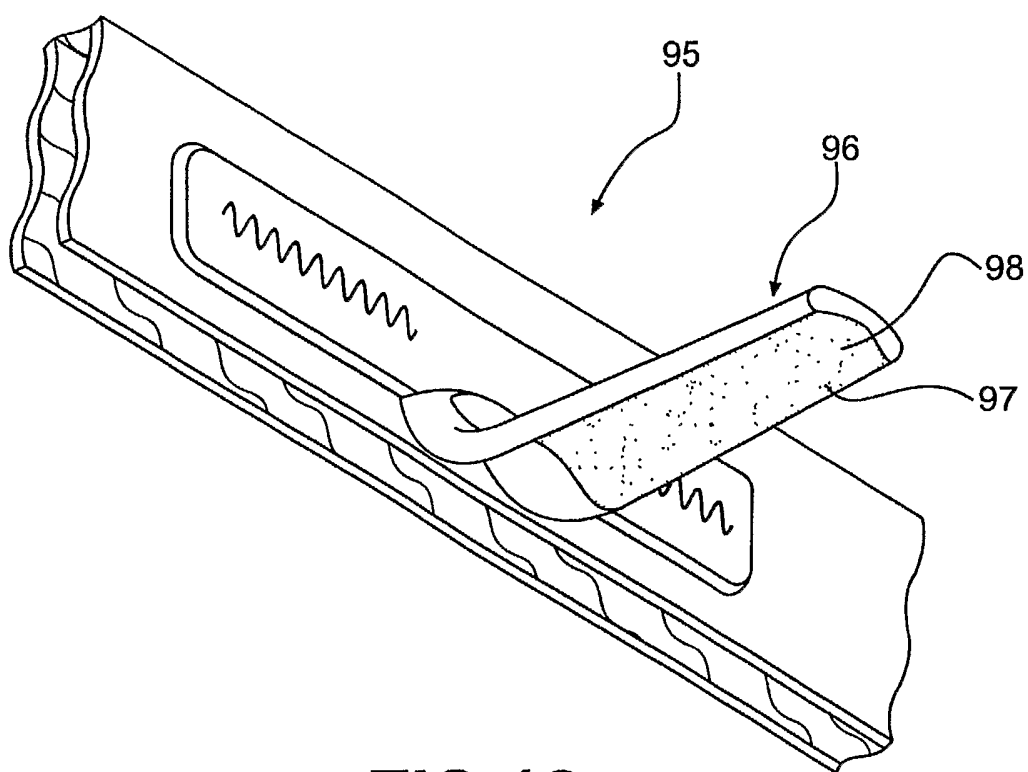




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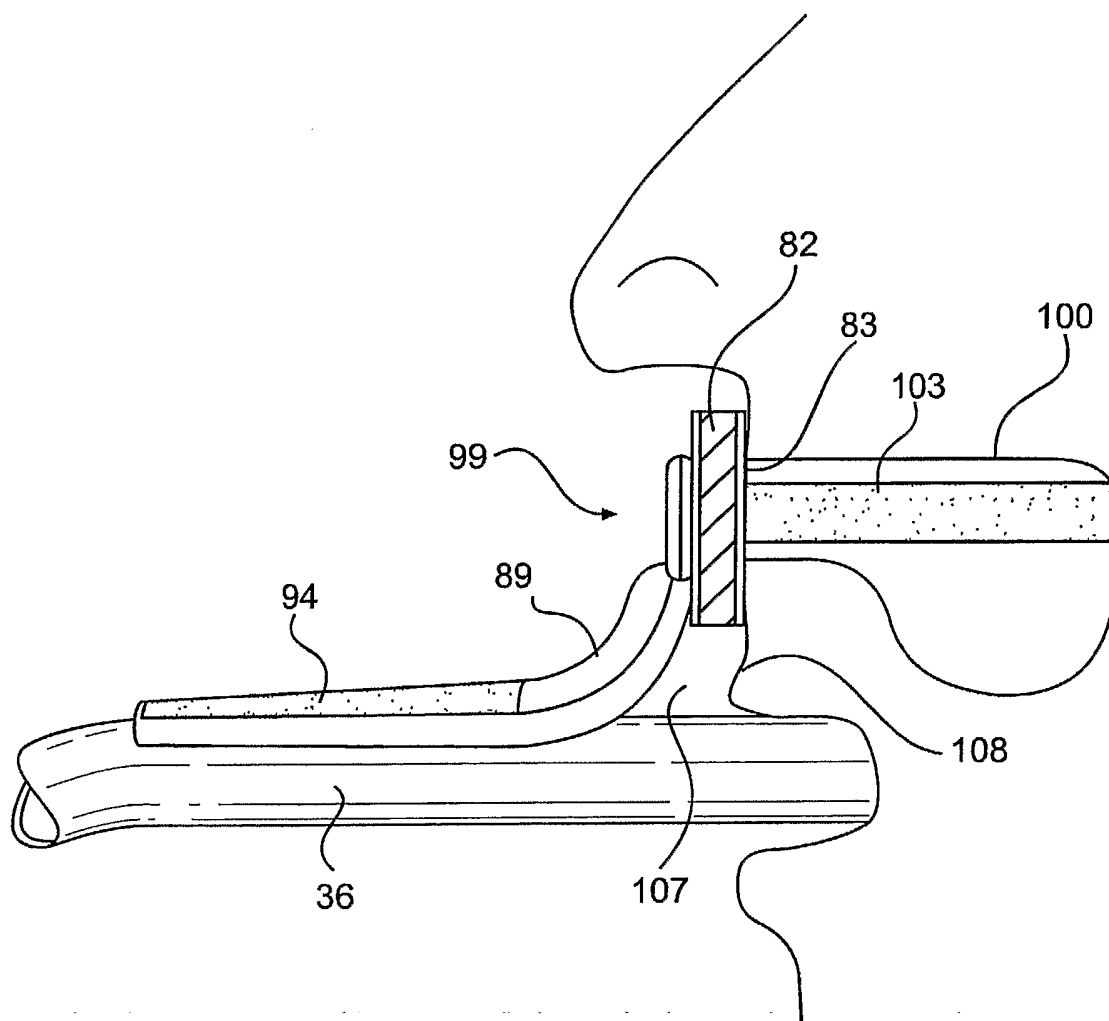
**FIG. 11**

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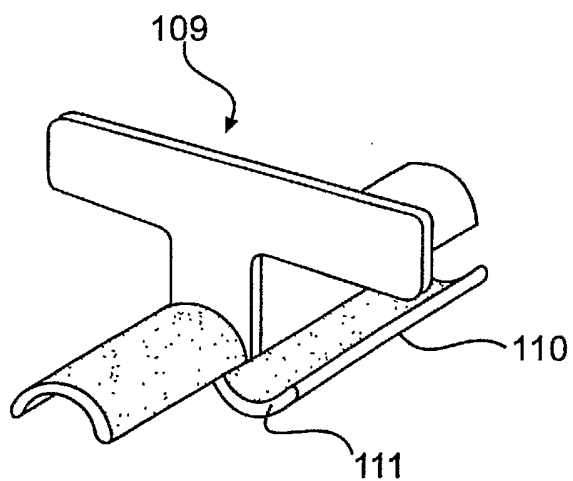


**FIG. 12**

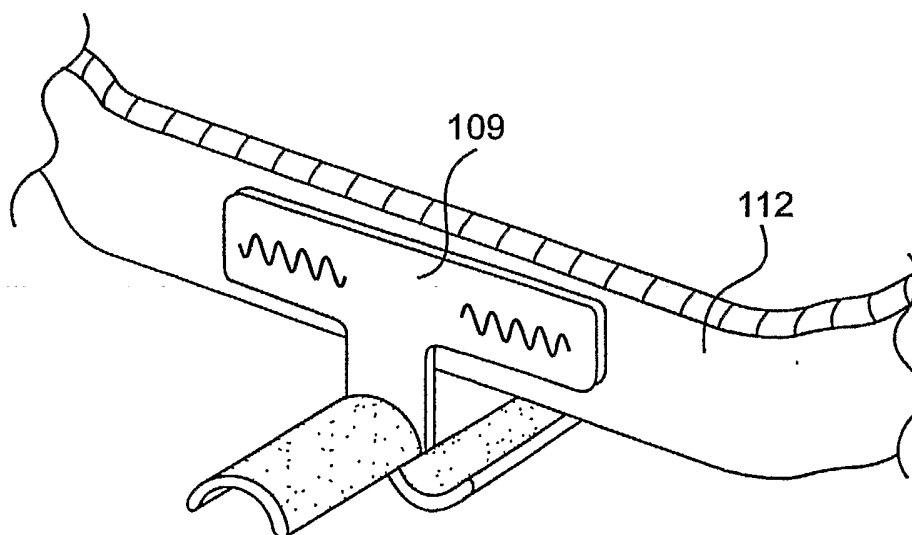
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**FIG.13**

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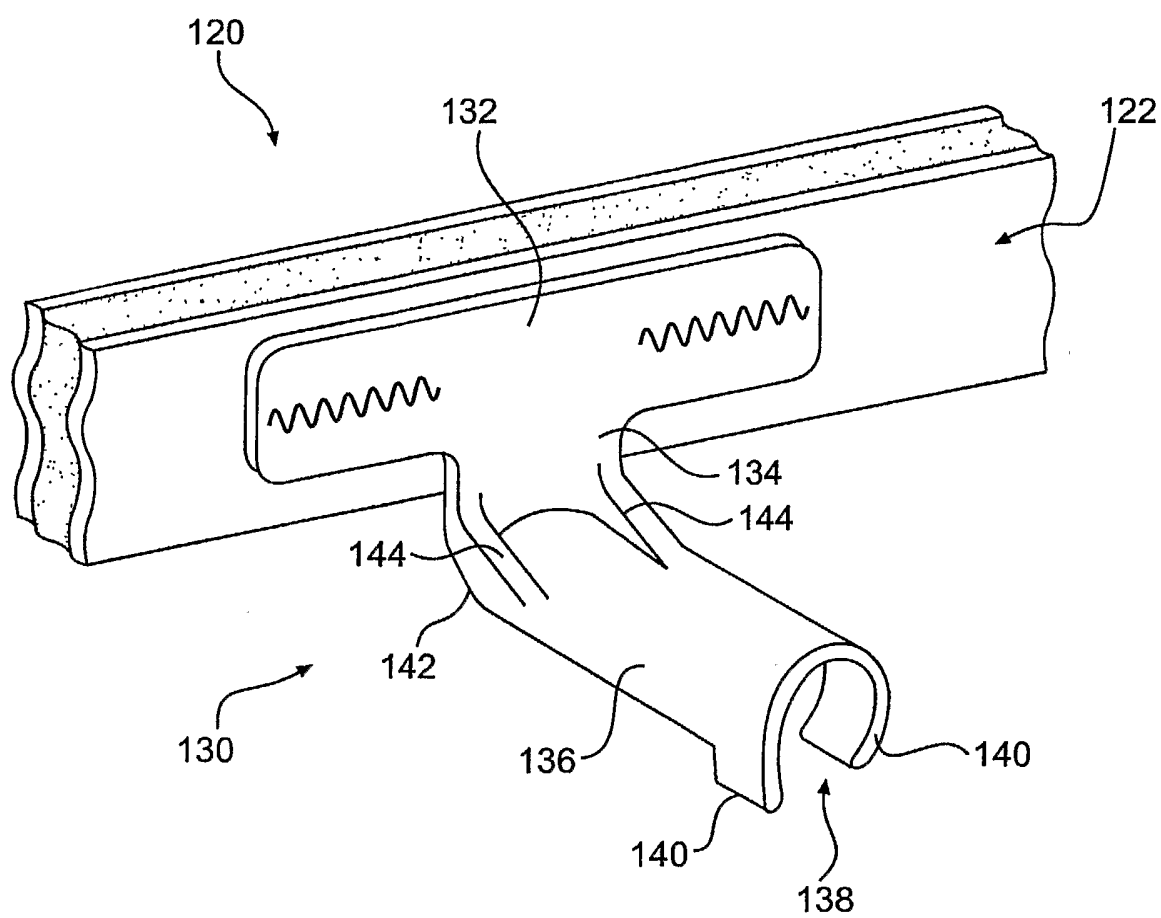


**FIG. 14**



**FIG. 15**

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**FIG. 16**

## INTERNATIONAL SEARCH REPORT

International application No

/US2005/044200

## A. CLASSIFICATION OF SUBJECT MATTER

A61M16/04 A61B1/24 A61M25/02 A62B9/06

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M A61B A62B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 490 504 A (VRONA ET AL) 13 February 1996 (1996-02-13) the whole document -----	1-34
X	US 4 331 143 A (FOSTER ET AL) 25 May 1982 (1982-05-25) the whole document -----	34
X	US 5 558 090 A (JAMES ET AL) 24 September 1996 (1996-09-24) the whole document -----	34
A	US 4 592 351 A (SMITH ET AL) 3 June 1986 (1986-06-03) column 2, line 60 - column 3, line 20; figure 2 ----- -/--	6-11



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See patent family annex.

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Date of the actual completion of the international search

21 March 2006

Date of mailing of the international search report

03/04/2006

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## INTERNATIONAL SEARCH REPORT

international application No

PCT/US2005/044200

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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International application No

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